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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,476	02/27/2002	Roger N. Piasio	ISA-102.01	4777
63767	7590	01/24/2008		
FOLEY HOAG, LLP PATENT GROUP (w/ISA) 155 SEAPORT BLVD. BOSTON, MA 02210-2600			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/083,476

Applicant(s)

PIASIO ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22 is/~~are~~ pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 is/~~are~~ rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Request for Continued Examination**

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 10/29/07 has been entered.

### **Applicants' Amendment**

2) Acknowledgment is made of Applicants' amendment filed 10/29/07 in response to the final Office Action mailed 08/27/07.

### **Status of Claims**

3) Claim 22 has been amended via the amendment filed 10/29/07.  
Claim 22 is pending.

### **Prior Citation of Title 35 Sections**

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Abstract**

6) The abstract of the disclosure is objected to because it is presented in two paragraphs and includes more than 150 words. Correction is required. See MPEP § 608.01(b). Note that the abstract should be limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

### **Objection(s) Maintained**

7) The objection to the specification made in paragraph 3 of the Office Action mailed 7/27/04 and maintained in paragraph 8 of the Office Action mailed 12/29/05, paragraph 6 of the Office

Action mailed 12/05/06 and paragraph 8 of the Office Action mailed 08/27/07, is still maintained for reasons set forth therein.

### **Rejection(s) Withdrawn**

8) The rejection of claim 22 made in paragraph 14(g) of the Office Action mailed 12/05/06 and maintained in paragraph 16 of the Office Action mailed 08/27/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

9) The rejection of claim 22 made in paragraphs 18(a), 18(b) and 18(c) of the Office Action mailed 08/27/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

### **Rejection(s) Maintained**

10) The rejection of claim 22 made in paragraph 17 of the Office Action mailed 08/27/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is maintained for part of the reasons set forth therein and the reasons set forth herein below.

It is noted that Applicants have deleted the limitations 'non-bound complexes' and 'complexes' from the claim.

With regard to the identified phrase 'tagged antibody having been present in a dried state on the bibulous strip', Applicants contend that lines 2-4 of page 9 of the specification state that the 'strip has .... a deposit of tagged purified antibody conjugate located immediately ahead of the sample receiving zone, which deposit is rendered flowable by contact with liquid sample'.

Applicants argue that a deposit of tagged antibody on a strip that is 'rendered flowable by contact with liquid sample' must be in a 'dried state' before the liquid sample mobilizes it and thus there is support for the term 'dried state' in the specification. Applicants assert that the term 'dried state' makes the claim easier to understand and shorter. Applicants cite MPEP 2163.02 and state that the subject matter of the claim need not be described literally using the same terms or in *haec verba*.

Applicants further point to lines 9-12 of page 9 of the specification and state that the sample is a 'mixture' of tagged antibodies and the liquid sample itself in which 'conjugates of tagged antibody and target antigen form' i.e., complexes form in this mixture. With regard to the limitation 'at least one scrub zone', Applicants state that the concept of having at least one scrub zone on the strip is literally present in the specification in Examples 3 and 4.

Applicants' arguments have been carefully considered, but are not persuasive. Lines 2-4 of page 9 of the specification are reproduced below:

strip has a sample receiving zone at one end, a deposit of tagged purified antibody conjugate located immediately ahead of the sample receiving zone, which deposit is rendered flowable by contact with liquid sample, a region through which sample and tagged purified antibodies flow

This part of the specification thus describes the strip to be having a sample receiving zone at one end, a deposit of --purified-- tagged antibody conjugate located immediately ahead of the sample zone, which deposit is rendered flowable by contact with liquid sample. Contrary to Applicants' argument, a deposit of tagged antibody on a strip that is 'rendered flowable by contact with liquid sample' need not be in a 'dried state', since the phrase also encompasses non-dried non-flowing deposit of purified or non-purified antibody conjugate that can also be rendered flowable by contact with a liquid sample. Furthermore, this part of the specification is limited to the deposit of --purified-- tagged antibody conjugate and it does not limit said tagged antibody to be present in a 'dried state' anywhere along or on the bibulous test strip, but on the bibulous strip immediately ahead of the sample receiving zone. The original claim 9 recited 'at least one immovable 'scrub' line. While Examples 3 and 4 and the abstract of the instant specification are supportive of the limitation 'at least one scrub line', these parts of the specification do not support any scrub 'zone'. Additionally, there is no descriptive support in the specification for the limitations: 'capture zone downstream of the at least one scrub zone' and 'a symptomatic *Streptococcus pneumoniae* infection'. The original claim 9 recited 'at least one immovable 'scrub' line located just prior to the capture line in the sample flow path'. The rejection stands.

#### **Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)**

**11)** Claim 22, as amended, is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As amended, the previously recited phrases in claim 22: 'complexes in the mixture'; 'at least one of the complexes if present'; 'including the complexes if formed'; and 'the mixture comprising any non-bound complexes' are now replaced with the phrases 'conjugates in the mixture'; 'at least one of the conjugates if present'; 'including the conjugates if formed'; and

'conjugates that have not bound to the antibodies specific for the conjugates immobilized in at least one scrub zone' respectively. Claim 22, as amended, further includes the newly added phrase in the last part of the claim: 'of any such conjugates to the antibodies specific for the conjugates immobilized in a capture zone downstream of the at least one scrub zone'. Applicants point to lines 9-13 of page 9 of the specification and state that the sample is a 'mixture' of tagged antibodies and the liquid sample itself in which 'conjugates of tagged antibody and target antigen form' i.e., complexes form in this mixture. Applicants submit that the antibodies described therein must be 'specific' for the complexes or conjugates if they are able to bind them. Applicants cite MPEP 2163.02 and state that the subject matter of the claim need not be described literally, i.e., using the same terms or in haec verba. Lines 9-14 of page 9 of the specification are reproduced below:

changes developed along the capture line and the control line. When the test is run and the target bacterial antigen is present in the liquid sample, after the sample is applied to the strip and picks up the tagged antibodies as it flows along, conjugates of tagged antibody and target antigen form during further flow to the capture line, where tagged antibody-target antigen-fixed antibody "sandwiches" form and become visible as a result of the massing of tag along the fixed capture line.

This part of the specification however does not provide descriptive support for 'at least one of the conjugates', and for a mixture comprising any conjugates 'that have not bound to the antibodies .....'. Note that the limitation 'at least one' has no upper limit, has a lower limit of one, but also encompasses two, three, four etc. The negative limitation in the claim 'conjugates that have not been bound to the antibodies ...' lacks descriptive support in the specification, as originally filed. Furthermore, since the antibodies recited are not purified, their binding to an antigen or conjugate need not be 'specific', but can be non-specific. Furthermore, the method as claimed includes the step of immobilizing a tagged antibody capable of binding the C-polysaccharide antigen following the step of flowing the urine sample anywhere along the bibulous test strip, for which there appears to be no support in the specification. Therefore, the above-identified limitations in the amended claim and the current scope of the claim are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or alternatively, remove the new matter from the claim(s).

Applicants should specifically point out the support for any amendments made to the disclosure.  
See MPEP 714.02 and 2163.06.

**Rejection(s) under 35 U.S.C § 112, Second Paragraph**

**12)** Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 22, as amended, lacks proper antecedent basis in the limitation: ‘a human subject of age 12 years or less’ (see lines 3 and 4). Since line 2 of the claim already includes this limitation, for proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --said human subject of age 12 years or less--.

(b) Claim 22, as amended, is indefinite and confusing in the limitation: ‘antibodies specific for the conjugates immobilized’ (see lines 13 and 14), because it is unclear whether what are immobilized are the conjugates or the antibodies specific for the conjugates. If the latter is the case, it is suggested that Applicants replace the limitation with --antibodies specific for the conjugates, said antibodies immobilized--.

(c) Claim 22, as amended, is indefinite, confusing, and appears to lack antecedent basis in the limitation: ‘any conjugates that have not bound to the antibodies specific for the conjugates immobilized ..... scrub zone’ (see lines 19 and 20). Are these conjugates different from the ones recited in lines 15 and 16 of the claim? If not, it is suggested that Applicants provide proper antecedent basis to the limitation by replacing it with --said conjugates that have not bound to the antibodies specific for the conjugates immobilized ..... scrub zone--.

(d) Analogous rejection and criticism apply to the amended claim 22 with regard to the limitation: ‘any such conjugates to the antibodies specific for the conjugates immobilized in a capture zone downstream of the ..... scrub zone’ (see lines 21-23).

(e) Claim 22, as amended, is indefinite, confusing, and appears to lack antecedent basis in the limitation: ‘a capture zone’ (see line 22). Is this ‘a capture zone’ different from the one recited in line 18? If not, it is suggested that Applicants provide proper antecedent basis to the limitation by replacing it with --the capture zone--.

(f) For clarity and for the purpose of distinctly claiming the subject matter, it is

suggested that Applicants replace the limitation 'binding' all through the amended claim 22, with the limitation --allowing the binding of--.

### Remarks

- 13)** Claim 22 stands rejected.
- 14)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.
- 15)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.
- 16)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (571) 272-0898.

January, 2008

  
S. DEVI, PH.D.  
PRIMARY EXAMINER